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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,840	09/13/2000	Paul Remijan	VSI-005AX	7821
=	WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109		EXAMINER	
TEN POST OF			LEUBECKER, JOHN P	
bos ion, ma	02109		ART UNIT PAPER NUMBER	
			3779	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
Office Action Ownerson	09/660,840	REMIJAN ET AL.	
Office Action Summary	Examiner	Art Unit	
	John P. Leubecker	3779	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence ad	idress
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	J. lely filed the mailing date of this c (35 U.S.C. § 133).	
Status			
1) ☐ Responsive to communication(s) filed on <u>09 Not</u> 2a) ☐ This action is FINAL . 2b) ☐ This 3) ☐ Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro		e merits is
Disposition of Claims			
4) ☐ Claim(s) 1-18,22-33,35,39,43-51 and 59-90 is/8 4a) Of the above claim(s) 43-50 and 70-80 is/8 5) ☐ Claim(s) 1-18,22-33,35,39,81,82 and 84-90 is/8 6) ☐ Claim(s) 51,59-69 and 83 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	re withdrawn from consideration. are allowed.		
Application Papers			
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original original access access to the second or declaration is objected to by the Example 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 Cl	` ,
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicati ity documents have been receive I (PCT Rule 17.2(a)).	on No ed in this National	Stage
Attachment(s) 1)	4) 🔲 Interview Summary		
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite	

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Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2010 has been entered.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 51, 62 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 51, recitation of "a light source coupled to a fiber optic device within the handle" is unclear as to whether it is the light source and /or the fiber optic device that is "within the handle". For purposes of examination, it will be assumed that it is ONLY the fiber optic device that is "within the handle" (based on other amendments to the claims and the 112 first paragraph rejection made in the Action mailed December 9, 2009).

As to claim 62, term "lamp" lacks antecedent basis.

As to claim 83, this claim does not depend on a preceding claim.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 51 and 60, 61 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302) and further in view of Kurtzer (U.S. Pat. 5,168,863), Santangelo et al. (U.S. Pat. 4,610,242)

As to claim 51, Siegmund et al. discloses a rigid probe including an optical waveguide (1), a concentric fiberoptic illumination channel (25, col.4, lines 26-28), a handle (3,27) removably attached (via threads 39, such coupling anticipating first and second coupling elements) to the probe, a light source (33) that is optically coupled to the illumination channel within the handle via a fiber optic reducer (29), an optical lens element (5, which can be a positive lens, negative lens or lens system (col.4, lines 9-10), such lens system would encompass a first and second lens; in addition note Figs. 8a-8c and 9) coupled to the distal end of the waveguide, an optical relay (17) mounted in the handle (Fig.1) and optically coupled to a proximal end of the waveguide, and an imaging device (CCD camera) mounted in the handle at a proximal end of the optical relay.

Siegmund et al. fails to specify the length and diameter of optical waveguide. However, analogous miniature endoscopes (note Allred, III, Figure 2, col. 4, lines 28-34) are known to

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between 3.3 cm and 11 cm¹. Since Siegmund et al. fails to teach any particular length and diameter, it would have been obvious to one of ordinary skill in the art to have made the waveguide any desired diameter and length to meet the particular requirements for a certain procedure, and specifically, any length and diameter contemplated in the prior art, since such contemplation suggests a particular need or use for those dimensions in the prior art. Clearly a diameter of less than 2 mm, as taught by Allred, III would encompass the diameters 0.6 mm to 1.6 mm.

Siegmund et al. further fails to disclose a sterile disposable sheath attached to the probe and extending over the handle. However, Kurtzer teaches an analogous endoscope having such sheath (20). It would have been obvious to one of ordinary skill in the art to have provided a sheath over the handle of Siegmund et al. to provide a sterile barrier between the handle/camera and the patient to protect the patient from any contamination from elements of the device which are normally handle by the surgeon and to protect the handle/camera from contamination from the patient (e.g., fluids, bacteria).

Siegmund et al. discloses the endoscope as claimed but further fails to disclose a separate cannula that receives the distal end of the probe such that the outer sheath (37) slides within the cannula and that the cannula has a locking mechanism at a proximal end that attaches to the probe. Santangelo et al. demonstrates what is conventional in the endoscope art in that endoscopes are known to be used with a cannula and trocar (stylet) for providing an entry site for the endoscope into the body through the skin (col.1, lines 14-35). Santangelo et al. teaches such

¹ The probe sleeve (18) is about 3.3 cm in length and the main housing (12) about 7.5 cm in length. Since the

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cannula/trocar combination (Figs.2,3) wherein the cannula (18,20, Fig.1) includes a locking mechanism (30 in Fig.1 or 31'/36' in Fig.11) at a proximal end to attach to a hub (22) of the endoscope. In addition, Santengelo et al. further teaches a fluid delivery port (51,col.4, lines 62-64) on the cannula for introducing or aspirating fluid through the cannula. It would have been obvious to one of ordinary skill in the endoscope art to have used the endoscope of Siegmund et al. with the cannula/trocar arrangement of Santangelo et al., if not for the fact that such combination of devices are known and used, for the purpose of providing an entry site into the patient (col.1, lines 29-30), protecting the distal end of the endoscope (col.1, lines 41-45) and allowing quick and easily insertion of the endoscope to a proper axial and rotational position (col.1, line 69 to col.2, line 6).

As to claim 60, note ring of optical fibers (25). As to claim 61, the light source is optically connected to the fiber optic coupling element (29, Fig.1) which constitutes a fibers optic reducer due to the narrower distal portions of such element. As to claims 63 and 64, note in Kurtzer that the sterile barrier (20) is attached to the probe via a disposable probe element (13, Fig.6, col.5, lines 37-59). As to claim 65, note locking mechanism (30) mentioned above with respect to Santangelo et al. As to claim 66, probe would fit within the cannula as noted above with respect to Santangelo et al. As to claim 67, note col.6, lines 17-26 regarding a locking mechanism (70) and further note the locking mechanism of Santangelo et al. As to claim 68, the cannula tip (21) forms a needle (note tapered pointed end 21, Fig.1of Santangelo). As to claim 69, the trocar (60, Fig.3) constitutes a stylet.

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6. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302), Kurtzer (U.S. Pat. 5,168,863), and Santangelo et al. (U.S. Pat. 4,610,242), as described above and further in view of Ohshiro (U.S. Pat. 4,569,334).

Siegmund et al., as described above, fails to disclose the thickness of the illumination waveguide. The thickness of such (e.g., distance between sheath 53 and image guide 1 in Figure 6a) depends on the diameters of the optical fibers making up the waveguide. Optical fibers can have a diameter of at least one millimeter to as small as 10 micrometers. Ohshiro teaches that illumination waveguides can comprise multiple fibers each having a diameter as small as 10 micrometers. Given these dimensions, a thickness of illumination waveguide of Siegmund being 0.1 to 0.2 mm is contemplated in the art and would have been obvious to one of ordinary skill since known optical fiber diameters would encompass the claimed thickness.

7. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Allred, III (U.S. Pat. 4,854,302), Kurtzer (U.S. Pat. 5,168,863), and Santangelo et al. (U.S. Pat. 4,610,242), as described above and further in view of Koeda et al. (U.S. Pat. 5,746,494).

Siegmund et al., as described above, fails to disclose the particulars of the connection between the light source (33) and the illumination waveguide. Koeda et al. is just one of numerous examples of the level of ordinary skill in the art regarding the coupling of a light source with an optical fiber. Koeda et al. teaches use of a lens (111c or 114, Fig.4) for coupling

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light from a lamp to a fiber optic bundle to provide a efficient coupling while maintaining good

luminous intensity distribution characteristics (col.2, lines 10-15). It would have been obvious to

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have provided a lens for coupling light from a light source to an optical fiber for the desirable

reasons set forth above.

Allowable Subject Matter

8. Claims 1-18, 22-33, 35, 39, 81, 82, 84-90 are allowed.

9. Claim 83 would be allowable if rewritten to overcome the rejection(s) under 35

U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of

the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments filed November 9, 2010 have been fully considered but they are

not persuasive.

All claims have been considered in view of Applicant's arguments. New rejections where

appropriate appear above.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

US 5630783 A Steinberg; Jeffrey

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US 5800343 A Takeuchi; Shinji et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas J. Sweet can be reached on (571) 272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/ Primary Examiner Art Unit 3779

jpl